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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/806,522

03/23/2004

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340.182

2749

27019 7590 03/17/2008
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EXAMINER

JONES, DAMERON LEVEST

ART UNIT

PAPER NUMBER

1618

MAIL DATE

DELIVERY MODE

03/17/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/806,522	Applicant(s) SHAHEEN ET AL.	
	Examiner D. L. Jones	Art Unit 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 3/23/04 & 11/1/07.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) 1-24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>3/23/04</u> . | 6) <input type="checkbox"/> Other: _____ |

APPLICANT'S INVENTION

1. Applicant's invention is directed to an in vivo method of testing allergic response in animals comprising subcutaneously injecting allergens treated with a hypohalous acid solution.

Note: Claims 1-25 are pending.

RESPONSE TO APPLICANT'S ELECTION

2. Applicant's election without traverse of Group III (claim 25) in the reply filed on 11/1/07 is acknowledged.

Note: Applicant is respectfully requested to cancel the non-elected subject matter.

112 FIRST PARAGRAPH REJECTIONS (Written Description)

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claim 25 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant is reminded that an inventor must describe the item to be patented with such clarity that the reader is assured that the inventor actually has possession and knowledge of the unique composition/method that makes the invention worthy of patent

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protection. What the reader learns from this patent application is a plan for obtaining a desired result. In particular, while the patent application calls for the use of a composition comprising allergens treated with a hypohalous acid or salt thereof for testing an allergic response, the specification does not identify the allergic response being tested, using the allergen treated with a hypohalous acid or salt thereof.

In order to satisfy the written description requirement, the specification must describe every element of the claimed invention in sufficient detail so that one of ordinary skill in the art would recognize that the inventor possessed the claimed invention at the time of filing. In this application, it appears that the application does no more than describe the desired function of the composition called for and contains no information by which a person of ordinary skill in the art would understand the concentration of hypohalous acid or salt thereof, allergen/allergens, or allergies being tested in the invention.

112 FIRST PARAGRAPH REJECTIONS (Scope of Enablement)

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claim 25 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

There are several guidelines when determining if the specification of an application allows the skilled artisan to practice the invention without undue experimentation. The factors to be considered in determining what constitutes undue experimentation were affirmed by the court in *In re Wands* (8 USPQ2d 1400 (CAFC 1986)). These factors are (1) nature of the invention; (2) state of the prior art; (3) level of one of ordinary skill in the art; (4) level of predictability in the art; (5) amount of direction and guidance provided by the inventor; (6) existence of working examples; (7) breadth of claims; and (8) quantity of experimentation needed to make or use the invention based on the content of the disclosure.

(1) Nature of the invention

Claim 25 is directed to an in vivo test method for testing allergic response in animals comprising subcutaneously injecting a composition comprising an allergen treated with a hypohalous acid or salt thereof.

(2) State of the prior art

The state of the prior art is such that it is known in the art to administer a hypohalite solution (i.e., sodium hypochlorite) to a subject (see Camper et al, US Patent No. 6,589,568, column 1, lines 63-67 and column 2, lines 1-5); however, the administering of a hypohalite solution in combination with an allergen is not known in the art. In addition, the state of the prior art as it relates to hypohalite solutions, specifically, hypochlorite solutions, indicate that the concentration of the hypochlorite solution is critical since, concentrated hypochlorite, for example, would result in damaging effects to the subject. Hostynek et al (Contact Dermatitis, 1990, Vol. 23, pp.

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316-324) disclose that skin irritation could be seen in subjects depending on the amount of hypochlorite present in the solutions (see abstract; page 317, Table 1; page 318, Table 2; page 319, Figures 1 and 2; page 320, Table 3).

Rutala et al (cited on the information disclosure statement, *Infect. Control Hosp. Epidemiol.*, 1998, Vol. 19, pp. 323-327) disclose that the concentration of hypohalous acids (i.e., hypochlorite) necessary to clean blood spills depend on the amount of organic matter present on the surface to be cleaned or disinfected. In addition, it is disclosed that hypochlorites are the most widely used chlorine disinfectants in the United States. However, their use in hospitals is limited by their corrosiveness, inactivation by organic matter, and instability. Decomposition of hypochlorite solutions results in a loss of available chlorine and a loss of antimicrobial activity. Decomposition of the hypochlorite solution is affected by several factors such as temperature, chlorine concentration, light, the presence of catalysts, and pH (see entire documents, especially, abstract; page 323, introduction; page 324, 'Results'; page 325, Table 1; Figures 1 and 2; page 326, Table 2; page 327, Figures 3 and 4). The existence of these obstacles establishes that the knowledge in the art would hinder one of ordinary skill in the art from accepting any regimen as being acceptable for in vivo testing of all allergic responses in subjects by administering a composition comprising an allergen in combination with a hypohalous acid or salt thereof. Furthermore, the skilled artisan would recognize that allergic reactions include runny nose, red eyes, skin rashes, sneezing, etc. Also, the skilled artisan would recognize that allergen include a multitude of possible substances that can cause an allergic reaction (i.e., mold, cats, dogs, birds,

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dust mites, etc.). Thus, there is a vast range of allergic responses that may occur based on the composition comprising the allergen and hypohalous acid or salt thereof.

(3) Level of one of ordinary skill in the art

The level of one of ordinary skill in the art is high. There is no evidence of record which would enable the skilled artisan in the identification of all the possible allergens and hypohalous acids or salts thereof that may be administered to a subject. Also, the allergic response in subject is highly unpredictable because subjects respond differently to allergens and/or hypohalous acids or salts thereof.

(4) Level of predictability in the art

The art pertaining to the allergens and how one responds to the allergen is highly unpredictable, especially, since depending upon the concentration of hypohalous acid or salt thereof, a subject may have some allergic response to the hypohalous acid or salt thereof and not the allergen itself. Determining the various types or classes of allergens, the hypohalous acid or salt thereof, the allergic response, and the concentration of the hypohalous acid or salt thereof requires various experimental procedures and without guidance that is applicable to all concentrations of hypohalous acids or salts thereof and allergens, there would be little predictability in performing the claimed invention.

(5) Amount of direction and guidance provided by the inventor

There is no evidence of record which would enable the skilled artisan in the identification of the people who have the potential of responding similarly to the same allergen and hypohalous acid or salt thereof composition when administered.

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Applicant's limited guidance does not enable the public to prepare such a numerous compositions comprising allergens-hypohalous acids or salts thereof encompassed by the claim. There is no directional guidance for the specific types of allergic responses subjects will express when administered the desired compositions.

(6) Existence of working examples

Independent claim 25 encompasses a vast number of allergic responses, allergens, and hypohalous acids and salts thereof. Applicant's limited working examples do not enable the public to prepare knowledge of such a numerous amount compositions and the suspected allergic reactions.

(7) Breadth of claims

The claims are extremely broad due to the vast number of possible allergic responses, hypohalous acids, and allergens known to exist. For example, possible allergens include those associated with roaches, pets, mold, pollen, dust mites, etc. Also, possible allergic responses include runny noses, sneezing, rashes, red eyes, etc..

(8) Quantity of experimentation needed to make or use the invention based on the content of the disclosure

The specification does not enable any person skilled in the art to which it pertains to make or use the invention commensurate in scope with the claims. In particular, the specification fails to enable the skilled artisan to practice the invention without undue experimentation. Furthermore, based on the unpredictable nature of the invention, the state of the prior art, and the extreme breadth of the claims, one skilled in the art could not perform the claimed invention without undue experimentation.

112 SECOND PARAGRAPH REJECTIONS

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claim 25 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claim as written is ambiguous because it is unclear what allergic response Applicant is testing for in the animals after having administered the composition comprising allergens and a hypohalous acid or hypohalous acid salt.

The claim as written is ambiguous because it is unclear what allergens Applicant is subcutaneously injecting into the animals.

The claim as written is ambiguous because it is unclear what hypohalous acid or salt thereof Applicant is referring to in the claim that is compatible with the instant invention.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. L. Jones whose telephone number is (571) 272-0617. The examiner can normally be reached on Mon.-Fri., 6:45 a.m. - 3:15 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/D. L. Jones/

D. L. Jones
Primary Examiner
Art Unit 1618

March 1, 2008